

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

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IN RE: ETHICON, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY LITIGATION

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: Master File No. 2:12-MD-02327

: MDL No. 2327

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THIS DOCUMENT RELATES TO ALL CASES

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: Hon. Joseph R. Goodwin, USDJ

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**CERTIFICATION IN SUPPORT OF  
MOTION TO INTERVENE TO SEEK STAY AND AMENDMENT OF PTO 190**

I, Garrie Richardson, being of full age, do hereby certify as follows:

1. I am President of SciSafe, Inc., a biological and pharmaceutical storage and cold chain logistics service, with its main offices located at 2540 U.S. Route 130, Cranbury, NJ 08512. SciSafe operates facilities in Cranbury, New Jersey and Billerica, Massachusetts.

2. I have been President of SciSafe since its inception in 2010, when it was created specifically to operate as a medical-legal storage and retrieval service with chain-of-custody security.

3. SciSafe currently manages storage of thousands of pieces of medical evidence on behalf of both plaintiffs and defendants in various types of litigation, both individual and mass-tort, including matters involving potentially defective drugs and medical devices. Many of the major MDL steering committees' members choose SciSafe as their evidence repository. In addition to numerous pharmaceutical products, SciSafe manages storage of medical devices such as IUDs, artificial hips, artificial knees, and all types of mesh.

4. SciSafe presently stores more than 250 Ethicon mesh explants on behalf of more

than 20 law firms in this litigation alone.

5. SciSafe is an FDA registered and audited facility (license number 3008798401) for the storage of human cell, tissue, and cellular and tissue-based products ("HCT/Ps"), offering its clients the highest levels of evidence storage, security and chain-of-custody documentation available. It is my understanding that we are the only storage facility in this market that is FDA licensed and regulated. SciSafe is fully compliant with FDA regulations and related Good Manufacturing Practices.

6. SciSafe is one of the leading medical-legal storage companies in the world, whose team consists of technical experts with decades of sample management, chain of custody and cold chain logistics experience in the most stringently regulated environments.

7. SciSafe's controlled-access facilities utilize specially designed temperature- and humidity-controlled rooms. They are monitored by CCTV and the chambers are equipped with alarms that notify staff in the event conditions are not within specifications. The SciSafe alarm system includes cellular backup, and the company maintains redundant systems for everything we do, with a full audit trail.

8. SciSafe employees are both HIPAA and GMP trained and certified.

9. Requiring transfer of materials stored at SciSafe to another repository will result in unnecessary additional costs to all parties. Allowing SciSafe to operate as an approved third-party repository will further assist in ensuring competitive pricing for storage and retrieval costs.

10. Requiring transfer of materials stored at SciSafe to another repository will result in unnecessary risk in the transport of materials from one site to another over a distance of more than 1500 miles, as well as requiring additional layers of chain of custody documentation

necessitated by the transfer.

11. Requiring storage of all materials for an entire MDL in a single location runs additional risks of losing all materials in the event of a catastrophic incident at the site.

12. Requiring transfer of materials stored at SciSafe to another repository will result in an unnecessary and highly detrimental loss of business to SciSafe that could amount to hundreds of thousands of dollars in revenue. While SciSafe does not have any vested interest in the outcome of this litigation, the conduct of discovery and evidence preservation with respect to explanted materials does have a direct effect on its business.

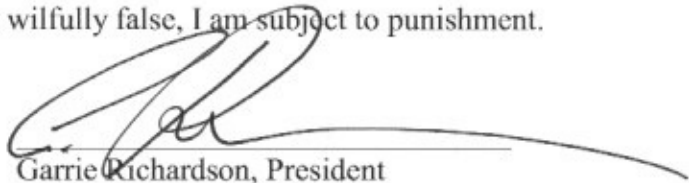
13. SciSafe stands ready to abide by all the protocols and procedures outlined in the Court's Pretrial Order #190 regarding preservation and testing of explants and tissue samples, in the event this Court were to grant the requested amendment and deem SciSafe an approved third-party repository in this litigation.

14. In the alternative, SciSafe requests a stay of the application of PTO 190 with respect to materials it holds in storage, in the event the parties or this Court should request further submissions and/or argument as to this application.

15. I make this Certification in support of SciSafe's motion to intervene to seek a stay and/or amendment of PTO 190 in this litigation.

16. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

Dated: October 5<sup>th</sup>, 2015

  
Garrie Richardson, President  
SciSafe, Inc.